California Health and Human Services Agency
Committee for the Protection of Human Subjects

DEATH DATA ONLY
New Project Application Review and Revision Checklist

Date: _____
Project Title: _____

Institutional Affiliation:_____
Principal Investigator (PI): _____
Mailing Address: _____
_____
Telephone: _____ Fax: _____ E-mail: _____

SHADED AREA IS FOR CPHS STAFF USE ONLY
Project Number:
Reviewer:
D t Rr:
Due Date:

Please check if your institution is:
☐ Governmental or
☐ Nonprofit
If your institution is not governmental or nonprofit, CPHS may not be able to review your project unless you are able to affiliate with a qualifying organization

Staff Reviewer
☐ Yes ☐ No
☐ Yes ☐ No

Have you included the following (please check)?

All Projects:	CPHS Staff:
☐ Cover Letter	☐ Yes ☐ No
☐ Death Data New Project Application Review and Revision Checklist	☐ Yes ☐ No
☐ Project Protocol	☐ Yes ☐ No
☐ Signature of P.I.(s) on New Project Application Review and Revision Checklist	☐ Yes ☐ No
☐ Signatures of P.I. and Responsible Official on Project Protocol	☐ Yes ☐ No
☐ C.V. of PI (new projects only)	☐ Yes ☐ No
☐ Other: Specify: _____ _____ _____	

Type of Review Requested (check one):

☐ New Project	☐ Yes ☐ No
☐ Revisions	☐ Yes ☐ No
☐ Completed	☐ Yes ☐ No
☐ Withdrawn	☐ Yes ☐ No

Use this page for New Projects Only. If this project is being submitted for revisions, please skip to page 3

THIS SHADED AREA FOR CPHS REVIEWERS ONLY
Project Number:
Reviewer Concurs:

1.	Does the protocol provide background information that justifies the need for the research?	☐ Yes ☐ No	☐ Yes ☐ No
2.	Will the study design adequately test the principal research questions of the study?	☐ Yes ☐ No	☐ Yes ☐ No
3.	Will the information requested be necessary and sufficient to answer the principal research questions?	☐ Yes ☐ No	☐ Yes ☐ No
4.	Will the privacy risks to the estates of deceased persons be appropriately minimized?	☐ Yes ☐ No	☐ Yes ☐ No
5..	Will the data be appropriately protected both during and after the completion of the project?	☐ Yes ☐ No	☐ Yes ☐ No
6.	Will the budget be adequate to complete the research?	☐ Yes ☐ No	☐ Yes ☐ No
7.	Is the principal investigator professionally qualified to carry out the research?	☐ Yes ☐ No	☐ Yes ☐ No

8. Check the box which indicates the nature of each department's involvement – i.e., funding, principal investigator (PI), research staff, or supplying human subjects (note that only subjects for whom the State has direct responsibility, e.g., mental hospital patients should be included).

Dept.	Funding	PI	Staff
Department of Alcohol and Drug Programs			
Department of Developmental Services			
Department of Health Care Services			
Department of Mental Health			
Department of Public Health			
Department of Social Services			
Office of Statewide Health Planning and Development			
Other			

DEATH DATA
Revisions Only

1. Are you requesting any changes to your approved protocol, including use of additional years of data?

☐**Yes** ☐ **No**

(***If "Yes",*** please specify and justify revisions and address whether revisions change subjects' risk level in the box below. Please attach copies of old protocol with tracked changes and clean copies of new protocol with original signatures from Principal Investigator (PI) and Responsible Official (RO).)

2. Are you proposing any new documents or changes to other project documents (e.g., consent forms, survey instruments, questionnaires, translations, etc.)?

☐**Yes** ☐ **No**

(***If "Yes,"*** please specify and justify revisions and address whether revisions change subjects' risk level in the box below. Attach old materials with tracked changes and clean copies of new materials and ensure protocol reflects changes, as appropriate.)

:

3. Are you requesting a change in PI.or RO?

☐**Yes** ☐ **No**

(***If "Yes",*** please specify the previous PI or RO and the new PI or RO in the box below. If a new PI is being added, address conflict of interest questions, including description of financial or other relationships that could be perceived as affecting objective research and the interpretation and publication of findings. Submit new PI's curriculum vitae. See Instructions for Researchers, Appendix I, #12 for financial relationship examples.)

PI's Signature: _____ **Date:** _____ **Project #:**_____

Name of PI (please type or print):_____

CPHS Use Only

STAFF:

☐ **New Project**
☐ **Revisions**
☐ **Completed**
☐ **Withdrawn**

Circle Reviewers:
Dickey Lowe Dinis Galbraith Harris Kirkish Mihordin Murphy Ruiz Snipes Ward Staff

REVIEWER:

If new project:
☐ Approved to use confidential Death Data ☐ Approval deferred, pending minor revisions (Comments)

If revisions:
☐ Yes ☐ No These revisions **are** minor
☐ Yes ☐ No These revisions **do not** increase risk to subjects
☐ Yes ☐ No. These revisions are **approved**
If No, is project referred to Full Committee? ☐ Yes ☐ No
Explain:

Completed or Withdrawn Project
☐ Yes ☐ No Is the plan for data destruction or return appropriate?
☐ Yes ☐ No Has PI provided sufficient information re: publications/reports?
☐ Yes ☐ No Are the reasons for withdrawal appropriate?
☐ Approved ☐Not approved, explain:

Comments:

If revisions required: ☐ Member must confirm revisions ☐ Staff may confirm revisions
☐CPHS staff approves revisions (initial and date):

CPHS Member or Staff Signature _____ **Date**_____

Please complete and fax to: CPHS Administrator Phone: 916-326-3660 Fax: 916-322-2512